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Applicant Initiated Interview Request Form

Application No.: 10/584,816 First Named Applicant: Bruce Reidenberg
Examiner: Kevin S. Orwig Art Unit: 1611 Status of Application: Pending

Tentative Participants:
(1) Oleg Ioselevich (2)_____

(3)_____ (4)_____

Proposed Date of Interview: November 18, 2010 **Proposed Time:** 11:00 PM (AM/PM)

Type of Interview Requested:
(1) [X] Telephonic (2) [ ] Personal (3) [ ] Video Conference

Exhibit To Be Shown or Demonstrated: [ ] YES [X] NO
If yes, provide brief description:_____

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1)_____	_____	_____	[ ]	[ ]	[ ]
(2)_____	_____	_____	[ ]	[ ]	[ ]
(3)_____	_____	_____	[ ]	[ ]	[ ]
(4)_____	_____	_____	[ ]	[ ]	[ ]

[ ] Continuation Sheet Attached
[X] Proposed Amendment or Arguments Attached
Brief Description of Arguments to be Presented:
Proposed claim amendments overcome 112, second paragraph, and 103(a) rejections

An interview was conducted on the above-identified application on _____.
NOTE: This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).
This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

/ /Oleg Ioselevich/
Applicant/Applicant's Representative Signature

Examiner/SPE Signature

Oleg Ioselevich
Typed/Printed Name of Applicant or Representative

56,963
Registration Number, if applicable

Listing of Claims

Claim 1 (currently amended): A transdermal delivery device comprising:

a drug containing layer comprising an analgesically effective amount of an opioid agonist and a plurality of microspheres dispersed in the drug containing layer,

the microspheres comprising a microemulsion of an opioid antagonist and being visually indiscernible in the drug containing layer.

Claim 2 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 1 to about 500 microns.

Claim 3 (currently amended): A transdermal delivery device comprising:

a drug containing layer comprising an analgesically effective amount of an opioid agonist and a plurality of microspheres dispersed in the drug containing layer,

the microspheres comprising an opioid antagonist and having a mean diameter of from about 1 to about 500 microns,

wherein the opioid antagonist is not releasable when the transdermal delivery device is applied topically intact to a skin of a human patient, and is releasable if the transdermal delivery device is administered intraoraly.

Claim 4 (previously presented): The transdermal delivery device of claim 3, wherein the microspheres have the mean diameter of from about 1 to about 300 microns.

Claim 5 (currently amended): The transdermal delivery device of claim 1, wherein the microspheres are multiphasic polymeric microspheres in which ~~comprise~~ the opioid antagonist is dispersed in oily droplets in a polymeric matrix of a polymer selected from the group consistinf of polyesters, polyethers, poly(orthoesters), polysaccharides, cyclodextrins, chitosans, poly(e-caprolactones), polyanhydrides, albumin, blends, copolymers thereof and mixtures thereof.

Claim 6 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres further comprise a polymer selected from the group consisting of

polyesters, polyethers, poly(orthoesters), polysaccharides, cyclodextrins, chitosans, poly(e-caprolactones), polyanhydrides, albumin, blends, copolymers thereof and mixtures thereof.

Claim 7 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres consist essentially of the opioid antagonist and a polymer selected from the group consisting of polyesters, polyethers, poly(orthoesters), polysaccharides, cyclodextrins, chitosans, poly(e-caprolactones), polyanhydrides, albumin, blends, copolymers and mixtures thereof.

Claim 8 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres consist essentially of the opioid antagonist dispersed in a polymeric matrix.

Claim 9 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 300 to about 500 microns.

Claim 10 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 200 to about 500 microns.

Claim 11 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 125 to about 200 microns.

Claim 12 (previously presented): The transdermal delivery device of claim 1, wherein the opioid antagonist is not releasable when the transdermal delivery device is applied topically intact to a skin of a human patient, and is releasable if the transdermal delivery device is chewed, soaked, punctured, torn, or subjected to any other treatment which disrupts the integrity of the microspheres.

Claim 13 (previously presented): The transdermal delivery device of claim 12, wherein the effect of the opioid agonist is at least partially blocked by the opioid antagonist when

the integrity of the microspheres is disrupted, and the disrupted microspheres are administered orally, intranasally, parenterally or sublingually.

Claims 14-17 (cancelled)

Claim 18 (previously presented): The transdermal delivery device of claim 1, wherein the opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof.

Claim 19 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 50 to about 100 microns.

Claim 20 (cancelled)

Claim 21 (previously presented): The transdermal delivery device of claim 1, wherein the drug containing layer is a matrix layer.

Claim 22 (currently amended): The transdermal delivery device of claim 21, where the matrix comprises a material selected from the group consisting of polyethylene, polypropylene, ethylene/propylene copolymers, ethylene/ethylacrylate copolymers, ethylenevinyl acetate copolymers, rubber, ~~rubber-like~~ synthetic homo-, co- or block polymers of rubber, polyacrylic esters and the copolymers thereof, polyurethanes, polyisobutylene, chlorinated polyethylene, polyvinylchloride, vinyl chloride-vinyl acetate copolymer, polymethacrylate polymer (hydrogel), polyvinylidene chloride, poly(ethylene terephthalate), ethylene-vinyl alcohol copolymer, ethylene vinyloxyethanol copolymer, silicone copolymers, cellulose polymers, polycarbonates, polytetrafluoroethylene and mixtures thereof.

Claim 23 (currently amended): The transdermal delivery device of claim 21 ~~claim 5~~, where the matrix comprises a polymer selected from the group consisting of silicone copolymers, silicone polymers that are cross-linkable, copolymers having dimethyl and/or dimethylvinyl siloxane units which can be crosslinked, block copolymers based on

styrene and 1,3-dienes, polyisobutylenes, and polymers based on acrylate and/or methacrylate.

Claims 24-30 (cancelled)

Claim 31 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 1 to about 200 microns.

Claim 32 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 1 to about 100 microns.

Claim 33-36. (Cancelled)

37 (new): The transdermal delivery device of claim 3, wherein the microspheres comprise a microemulsion of the opioid antagonist.